

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Claims 2-5, 7 and 9-16 have been amended to correct the antecedent basis of the preamble.

35 U.S.C. §112 Rejections

Claims 1-5, 7, 9-17, 19-23, 25-31 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written requirement.

Claims 1, 17, 19 and 28 have been amended to incorporate the language "such that lateral and longitudinal *flexibility* is improved" as disclosed in the specification in paragraph 0029. Therefore Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

35 U.S.C. §102 Rejections

Claims 1-5, 7, 9-17, 19-23, 25-31 have been rejected under 35 U.S.C. §102(b) as being anticipated by Pinchuk et al. (US Patent 5,968,091).

According to MPEP 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently disclosed, in a single prior art reference." Therefore Applicant will now address each of the Examiner's rejections individually.

1. "Referring to figure 7, Pinchuk et al teaches a modular stent comprising: A first stent module (a first plurality of zig-zags 34) defining a first passageway; at least a second stent module (a second plurality of zig-zags 36 adjacent to the first) defining a second passageway; and At least one polymer bridge in communication with the first and second module. See at least figure 7 and column 3, lines 20 et seq. Teaching a

polymeric coating and types of polymers over most of the stent including internal and external surfaces.” (See May 27, 2005 Office Action at page 4 line 6-14)

Pinchuk discloses polymer coatings from prior art stents including wire mesh stents and Wiktor-type stents. The Wiktor-type stent disclosed in Pinchuk is a single strand of zig-zag filament which is helically wrapped around a mandrel. The Wiktor-type stent is fully described in column 2 line 55 through column 3 line 2 of the Pinchuk patent as follows: “A Wiktor-type stent 30 is shown in prior art FIG. 4 in conjunction with a balloon catheter 31. The stent 30 is made of a single strand of zig-zag filament 32 which is helically wrapped around a mandrel. While the filament 32 does not necessarily cross over itself, adjacent zig-zags touch each other or come close to touching each other. One of the disadvantages of the Wiktor-type stent is that the zig-zag wire tends to expand non-uniformly when expanded in an artery by a balloon catheter. In addition, the non-braided stent can unfurl during maneuvering the balloon catheter in the vasculature which can cause placement problems as well as damage to the endothelium. In addition, the hoop strength of the Wiktor-type stent is relatively low.” Pinchuk provides a stent with increased hoop strength, that resists tapering and maintains flaring, exhibits little or no abrasion of wires in the vasculature and maintains a substantially constant diameter in the vessel by coating a conventional stent (including the Wiktor-type stent) with a polymer such that the polymeric coating binds the crossover points of the wires, or, in the case of a Wiktor-type stent, binds adjacent zig-zags of wires without occluding the interstices of the stent lattice (column 3 lines 9-27).

The Examiner states that he has interpreted Pinchuk “that a stent module comprises a first plurality of zig-zags 34, and more narrowly, the plurality of zig-zags forms approximately one turn; each approximate turn is a “module.” Applicants respectfully disagree with the Examiner’s interpretation of Pinchuk. In the stent art, the term modular stent has been used to define a stent in which discrete pieces, or modules, are combined with or attached to one another form a modular stent. An example of a stent module is disclosed in the instant application in Figure 2 and described in paragraphs 0029 and 0030. The stent modules disclosed in Figure 2 and paragraphs 0029 and 0030 are individual sections of stent material that are the joined

according to the teachings of the present invention. The turns of the Wiktor-type stent disclosed in Pinchuk are not modules according to the definition and use of the terms "module" and "modular" in the instant application. Applicants draw the Examiner's attention to Figures 1 and 2 from the instant application and Figure 7 of Pinchuk et al., which disclose the stent module of the instant application (Figure 2), a modular stent comprised of two stent modules of the instant application (Figure 1) and the zig-zag stent of Pinchuk (Figure 7). Applicants believe that a comparison of these two figures illustrates that the zig-zag stent represented in Figure 7 of Pinchuk is not a modular stent. These three figures are excerpted and provided for you herein as Appendix A.

Additionally, the problems with the Wiktor-type stent that Pinchuk addresses are not issues with the modular stent used in the instant application. Applicant's stent is comprised of stent modules which are joined together by the polymer coating. As disclosed in paragraph 0026 of the instant application, the radially expandable modular stent comprises at least two stent modules joined by at least one polymer bridge. Additionally, paragraph 0029 in the description of FIG. 3 discloses a second end of one stent module coupled to the first end of a second stent module by coating with polymer material. The stent modules may be coated with a polymer thereby forming a polymer bridge between the two stent modules. Modular stents are known in the art to provide improved flexibility over Wiktor-type stents due to their modular design. Applicant's stent does not have the problems listed for the Wiktor-type stent above. Pinchuk teaches coating stents for enhancement of stent hoop strength, not for lateral and longitudinal flexibility. Therefore independent claims 1, 17, 19 and 28 have been amended to add the language "having improved lateral and longitudinal flexibility" to the preamble and the limitation "such that lateral and longitudinal flexibility is improved." Support for these amendments can be found in paragraph 0029. No new matter was added as a result of the amendments to claims 1, 17, 19 and 28.

Therefore, because each and every element as set forth in the claims, namely "A radially expandable modular stent having improved lateral and longitudinal flexibility for implantation within the body of a patient, comprising: a first stent module defining a first passageway; at least a second stent module defining at least a second passageway;

and a least one polymer bridge in communication with said first stent module and at least said second stent module, said polymer bridge coupling said first stent module to at least said second stent module such that lateral and longitudinal stability is improved, wherein said first passageway and said at least said second passageway are in fluid communication,” was not found, either expressly or inherently, in the Pinchuk patent, the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

The polymer coating of the instant application is an integral part of the manufacture of this novel stent, rather than an attempt at improving functionality in an existing stent. Additionally, as the modular stent is not anticipated by Pinchuk et al, this point of rejection is moot and the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

2. “Regarding at least claim 7 requiring a polymer hinge defining a gap, see column 2, lines 60-63, teaching the modules can touch or not touch (producing a gap).” (See May 27, 2005 Office Action at page 4 line 15-16)

One feature of the stent of the instant application is the flexible hinge or gap that is formed between the second end of one stent module and the first end of a second stent module thereby permitting movement of the stent modules relative to each other and enhancing the lateral and longitudinal flexibility of the stent (paragraph 0029). The specification of the Pinchuk patent does not teach a stent in which stent modules are joined by a polymer bridge thereby permitting movement of the stent modules relative to each other. Additionally since Pinchuk *does not teach a modular stent*, this point of rejection is moot and at least claim 7 of the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

3. “Regarding the therapeutic agent, see column 4, lines 18 et seq.” (See May 27, 2005 Office Action at page 4 line 17)

Additionally since Pinchuk *does not teach a modular stent*, this point of rejection is moot and the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al.

4. "Regarding at least claim 13, see column 4, lines 28 et seq. (See May 27, 2005 Office Action at page 4 line 18)

Claim 13 states that the polymer bridge contains at least one radio-opaque or echogenic material. Radio-opaque is defined as "not penetrable by x-rays or other forms of radiant energy" (Dorland's Illustrated Medical Dictionary). Echogenic is defined as "in ultrasonography, giving rise to reflections (echoes) of ultrasound waves" (Dorland's Illustrated Medical Dictionary). Pinchuk et al do not disclose or teach including a material with radio-opaque or echogenic properties in the polymer coating. Therefore at least claim 13 of the instant application is not anticipated under 35 USC 102(b) by Pinchuk et al. By definition, radio-opaque and echogenic materials are not radioactive and are not beta- or gamma-emitters.

5. "Regarding claim 15, module is porous, see drug eluting reservoirs." (See May 27, 2005 Office Action at page 4 line 19)

The stents of the instant application can be manufactured from materials which are porous or non-porous and claim 15 has been amended as such. Support for this claim amendment can be found in paragraph 0026 of the specification. Therefore the Examiner's rejection is moot and claim 15 is not anticipated under 35 USC 102(b) by Pinchuk et al.

6. "Regarding claim 16, module is non-porous, the materials used to form the modules are non-porous." (See May 27, 2005 Office Action at page 4 line 20-21)

The stents of the instant application can be manufactured from materials which are porous or non-porous and claim 16 has been amended as such. Support for this claim amendment can be found in paragraph 0026 of the specification. Therefore the Examiner's rejection is moot and claim 16 is not anticipated under 35 USC 102(b) by Pinchuk et al.

7. "Regarding claim 25, see at least column 7, lines 60 et seq. (See May 27, 2005 Office Action at page 4 line 22)

Claim 25 has been cancelled, and therefore the Examiner's rejection is moot.

8. "Regarding the independent claims, it is the Examiner's position that the bridge of Pinchuk et al fulfills the functional language "such that the lateral and longitudinal stability is improved." (See May 27, 2005 Office Action at page 5 lines 1-3)

Independent claims 1, 17, 19 and 28 have been amended such that language that read "such that the lateral and longitudinal stability is improved" now reads "such that the lateral and longitudinal flexibility is improved." Pinchuk et al does not teach improving flexibility, therefore the claim amendments renders this rejection moot.

In conclusion, according to MPEP 2131 "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently disclosed, in a single prior art reference." As Pinchuk does not teach a modular stent and Pinchuk does not teach improving flexibility, Pinchuk does not teach the stent of the instant application and there the claims of the instant application are not anticipated under 35 USC 102(b) by Pinchuk et al..


The Examiner is respectfully requested to withdraw the rejections under 35 USC 102(b).

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 50-3207. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (949)253-0900.

Respectfully submitted,

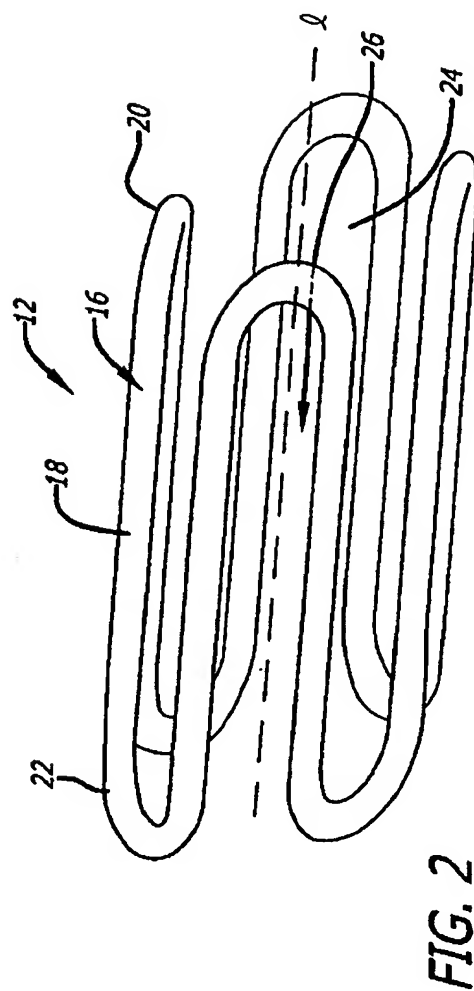
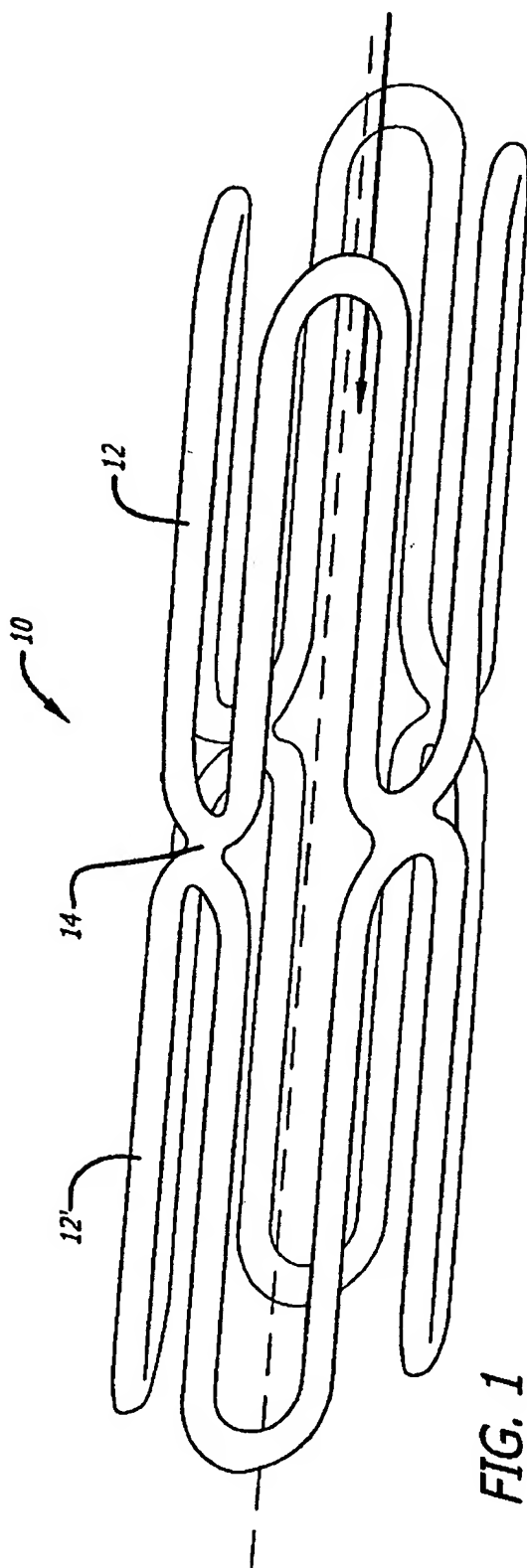
July, 27, 2005



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Amendment After Final
Application No. 10/731,968
Appendix A



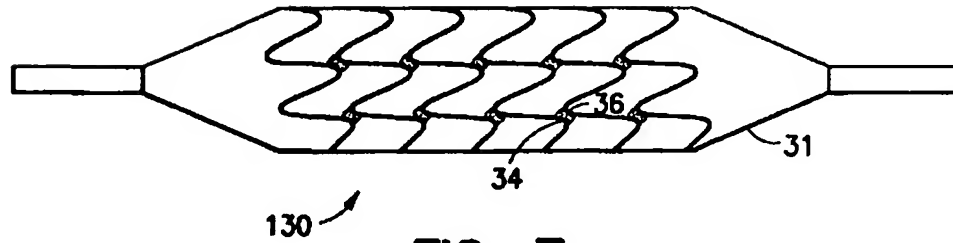


FIG. 7